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56. (New) The method in claim 55, in which the adjuvant is *Bacille Calmette-Guerin*.

Please cancel claims 1-12.

### REMARKS

This submission is in response to the Official Action dated April 10, 2002. Claims 1-24 are pending. Claims 21-24 are allowed. Claims 1-20 have been rejected. Claims 13,16,17, 18, 19 and 20 have been amended. Claims 1-12 have been cancelled. New claims 25-56 have been added. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

### Amended Claims

Claims 13,16,17, 18, 19 and 20 have been amended. Support for the amendments to Claim 13 is found in Claim 11 and 12 and in the application as filed at page 7, lines 18-2; page 20 lines 20 to 30 ,and Example 3. Amendments to Claims 16, 17, 18, 19 and 20 change inadvertent typographical errors in the dependencies. No new matter has been added in the amended claims.

### New Claims

New claims 25-52 include dependent claims to allowed claims 21-24 as well as independent claims. Support for the new claims is found in the claims as filed. In addition, support for the new claims is found in the application as filed. No new matter has been introduced.

Support for the new Claim 25 is found in Claim 11 as filed. Support for Claim 26 is found at page 30, lines 15-23 in the application as filed. Support for Claim 27, 28 and 29 is found at page 16 to page 19 of the application as filed. Support for Claim 30 is found at page 10-14 in the application as filed. Support for Claim 31 is found at 14-17 in the application as filed. Support for Claim 32, 33 and 34 is found at page 8-9 and in the Examples in the application as filed. Support for Claim 35, 36 and 37 is found at page 9 in the application as filed. Support for Claim 38 is found at page 23 in the application as filed. Support for Claim 39 is found at page 7, lines 18-21 of the application as filed. Support for Claim 40 is found at page 30 in the application as filed. Support for Claim 41 is found at page 3, lines 20-25 and page 7, lines 18-21, in the application as filed. Support for Claim 42 is found at page 7, lines 18-21, in the application as filed. Support for Claim 43 is found at page 23, lines 5-16 in the application as filed. Support for Claim 44 is found at page 3, lines 20-25 and page 7, lines 18-21, in the application as filed. Support for Claim 45 is found at page 30, lines 26-27. Support for Claim 46 is found in Claim 11 and 12 and in the application as filed at page 7, lines 18-2; page 20 lines 20 to 30, and Example 3. Support for Claim 47 is found at page 16 to page 19 of the application as filed. Support for Claim 48 and 49 is found at page 8-9 and in the Examples in the application as filed. Support for Claim 50 is found at page 23 in the application as filed. Support for Claim 51 is found at Claim 21 as filed in the original application as filed. Support for Claim 52-54 is the same as for Claims 48, 49 and 50. Support for Claims 55 can be found in Claim 23

as filed. Support for Claim 56 is found in claim 24 as filed.

No new matter has been added in the new claims.

Information Disclosure Statement

The examiner has invited submission of a PTO Form 1449, stating that a PTO Form 1449 was not enclosed with referenced filed June 6, 2001. In order to comply with the request for submission, a copy of the PTO Form 1449, filed on June 6, 2001 is attached at Tab A, along with a copy of returned post card listing said document.

35 USC §112

The Examiner has rejected claims 16-20 under 35 USC §112, second paragraph as failing to particularly point out and distinctly claim the subject matter the invention. Specifically, the Examiner rejected Claim 16 over a lack of antecedent basis in Claim 14. This results from an editing error. Claim 16 has been amended so that it now depends from Claim 15, a claim that provides proper antecedent basis for Claim 16.

In addition, the Examiner has rejected claims 12-14, 16, and 17-20 (all method claims) over a lack of proper antecedent basis in Claim 10 (a composition claim). This results from an editing error. Claims 16 and 17-20 have been amended

to change their dependency to Claim 13. Claim 13, as amended, is now an independent method claim which provides proper antecedent basis. Claim 14, due to amendments to Claim 13 now had proper antecedent basis. Since Claims 12 has been cancelled, a change in its dependency is not required.

In light of the amendments to Claims 16 and 17-20, and the cancellation of Claim 12, it is respectfully requested that the Examiner withdraw the rejection to the claims.

35 U.S.C. §102(b)

Martin, et al.

Claims 1-3, 6 and 9-12 are rejected under 35 U.S.C. §102(b) as anticipated by Martin, et al. (PNAS, 1971, Vol. 68, pp. 469-472). Claims 1-12 have been cancelled. Therefore, the rejections relating to Claims 1-3, 6, 9-12 are now moot. It is respectfully requested that the 35 U.S.C. §102(b) rejections based upon these claims be withdrawn.

35 U.S.C. §102(b)

Berd et al. (Ann. NY Acad. Sci.)

The Examiner has rejected claims 1-3, 6,7, 9,11 and 15 under 35 U.S.C. §102(b) as being anticipated by Berd et al., Ann. NY Acad. Sci., Vol. 690:147-152 (1993).

Claims 1-12 have been cancelled. Therefore, the rejections relating to Claims 1-3, 6, 7 and 9-11 are now moot. It is respectfully requested that the 35 U.S.C. §102(b) rejections based upon these claims be withdrawn.

Claim 13, as amended, recites that the first administration of tumor cells omits an adjuvant. The Berd et al., Ann. NY Acad. Sci., Vol. 690: 147-152 (1993) reference fails to disclose a method wherein the first administration of the tumor cell composition excludes an adjuvant. The methods of the reference utilize adjuvants in the first administration. Therefore, the reference, as recognized by the Examiner, does not disclose all the limitations of amended Claim 13.

In addition, since amended Claim 13 is not anticipated by the Berd et al., Ann NY Acad. Sci., Vol. 690:147-152 (1993) reference, it is axiomatic that Claim 15, which depends from Claim 13 and therefore contains all the limitations of Claim 13 is also not anticipated. Therefore, Claim 15 is not anticipated by the Berd reference.

It is therefore respectfully requested that the Examiner remove the 35 U.S.C. §102(b) rejection relating to Claim 15 allow the claims to pass to issuance.

35 U.S.C. §102(b)

Fujiwara

Claims 1, 2, 6, 9 and 10 are rejected under 35 U.S.C. §102(b) as being anticipated by Fujiwara, et al, The J. of Immun, Vol. 124:863-869(1980).

Claims 1-12 have been cancelled. Therefore, the rejections relating to Claims 1, 2, 6, 9 and 10 are now moot. It is respectfully requested that the 35 U.S.C. §102(b) rejections based upon these claims be removed.

35 U.S.C. §102(b)

Berd et al (WO 98/14206)

The Examiner has rejected claims 1-3, 6-11, under 35 U.S.C. §102(b) as being anticipated by Berd, et al.(WO 98/14206)

Claims 1-12 have been cancelled. Therefore, the rejections relating to Claims 1-3, 6-10 are now moot. It is respectfully requested that the 35 U.S.C. §102(b) rejections based upon these claims be removed.

35 U.S.C. §102(b)

Berd et al (WO 96/40173)

The Examiner has rejected claims 1-7, and 9-11 under 35 U.S.C. §102(b) as being anticipated by Berd, et al. (WO 96/40173).

Claims 1-12 have been cancelled. Therefore, the rejections relating to Claims 1-7, 9-11 are now moot. It is respectfully requested that the 35 U.S.C. §102(b) rejections based upon these claims be withdrawn.

Double Patenting

The Examiner has provisionally rejected Claims 1-3, 6-9 and 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,7, 8, 9,10 of co-pending U.S. Application No. 09/304,859. U.S. Application No. 09/304,859 has been allowed by the United States Patent and Trademark Office and the issue fee paid on August 6, 2002. It is respectfully pointed out to the Examiner that Claims 1-3, 6-9 and 11 of the pending application have been cancelled and the provisional rejection of these claims is now moot.

In addition, the Examiner has also provisionally rejected Claims 1-3, 6-9 and 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 7, 11, 16, 20, 21, 25, 53, 54, and 55 co-pending U.S. Application No. 09/025,012. It is brought to the notice of the Examiner that U.S. Application No. 09/025,012 is now abandoned. Furthermore, claims 1-3, 6-9, and 11 have been canceled. Therefore, it is respectfully requested that the Examiner remove the obviousness-type double patenting rejection for there will no risk of two patents issuing for the same invention.

#### Conclusions

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could

be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul F. Fehlner", written over a horizontal line.

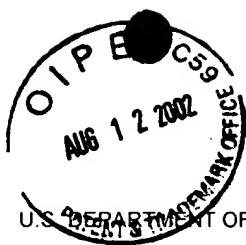
Paul F. Fehlner, Ph.D.

Reg. No. 35,135

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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT &amp; TRADEMARK OFFICE

SHEET 1 OF 2  
(REV. 7-80)**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 1225/1G584US2  
APPLICANT: David BERDSERIAL NO: 09/776,250  
FILING DATE: February 1, 2001  
CONFIRMATION NO:**RECEIVED**

AUG 21 2002

TECH CENTER 1600/2900

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIALS	NUMBER	DOCUMENT DATE	NAME	CLASS	SUBCLASS	FILING DATE
	1. 5,290,551	03/01/94	Berd			

**U.S. PATENT APPLICATIONS**

*EXAMINER INITIALS	APPLICATION NUMBER	NAME	FILING DATE
	2. 09/304,859	Berd	05/04/99

**FOREIGN PATENT DOCUMENTS**

*EXAMINER INITIALS	NUMBER	DOCUMENT DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	3. WO 00/38710	07/06/00	PCT			
	4. WO 00/31542	06/02/00	PCT			
	5. WO 00/29554	05/25/00	PCT			
	6. WO 00/09140	02/24/00	PCT			
	7. WO 99/56773	11/11/99	PCT			
	8. WO 99/52546	10/21/99	PCT			
	9. WO 99/40925	08/19/99	PCT			
	10. WO 98/14206	04/09/98	PCT			
	11. WO 96/40173	12/19/96	PCT			

**OTHER REFERENCES****(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

*EXAMINER INITIALS
12. Bach et al., J. Immunol., 1978;121(4):1460-1468
13. Berd et al., Cancer Res 1991;51:2731

**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 1225/1G584US2

SERIAL NO: 09/776,250

APPLICANT: David BERD

FILING DATE: February 1, 2001

CONFIRMATION NO:

\*EXAMINER  
INITIALS

14. Berd et al., Cancer Res 1986;46:2572

15. Miller and Claman, J. Immunol 1976;117(5):1519

16. Nahas and Leskowitz, Cellular Immunol., 1980;54:241-247

17. Röttschke et al., Nature 1990;348:252

18. Sato, Cancer Immunol Immunotherapy 1996;43:174

19. Sherman et al., J. Immunol., 1978;121:1432

20. Weigle, J. Exp. Med., 1965;122:1049-1063

EXAMINER: \_\_\_\_\_

DATE CONSIDERED: \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Return of this card properly stamped, will acknowledge receipt of:

Information Disclosure Statement; Form PTO-1449; Binder of  
References (1-20)

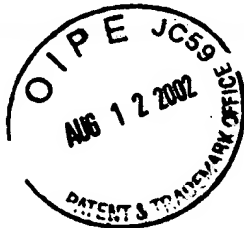
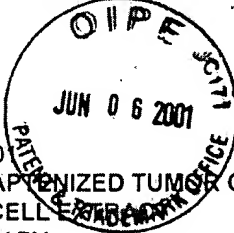
ALL ACCOMPANIED BY EXPRESS MAIL NO.

Applicant : David BERD  
Serial No. : 09/776,250  
Filed : February 1, 2001  
For : LOW DOSE HAPTOGENIZED TUMOR CELL  
AND TUMOR CELL  
IMMUNOTHERAPY

Attorney : PFF::AL:bar  
File No. : 1225/1G584US2 **6706742495-45**

Mailed : 6/6, 2001

Mailer: *B.W. Lee*



EXPRESS MAIL CERTIFICATE



Date 8-12-02 Label No. EV1157709894S  
I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

PATRICIA A. RYAN Patricia A. Ryan  
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PATENT TRADEMARK OFFICE

Docket No: 1225/1G584-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David Berd

Serial No.: 09/776,250

Art Unit: 1642

Confirmation No.: 8162

Filed: February 2, 2001

Examiner: CANELLA, KAREN

For: LOW DOSE HAPTENIZED TUMOR CELL AND TUMOR CELL EXTRACT  
IMMUNOTHERAPY

MARK-UP VERSION FOR AMENDMENT UNDER 37 C.F.R. §1.312

Hon. Commissioner of  
Patents and Trademarks  
Washington, DC 20231

August 12, 2002

IN THE CLAIMS:

13. (Amended) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient

a composition comprising a haptenized or non-haptenized tumor cell or tumor cell extract comprising from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells or cell equivalents per dose, without any adjuvant, wherein the tumor cells or cell equivalents are conjugated to a hapten, and rendered incapable of growth or multiplication in vivo, [The method of claim 10, wherein the composition is administered] prior to a second composition comprising an adjuvant and a tumor cell or tumor cell extract, which second composition [ a) is conjugated to a hapten, and b)](a) contains from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells or tumor cell equivalents and (b) wherein the tumor cell or tumor cell extracts are conjugated to a hapten.

16. (Amended) The method of claim [13]15, wherein the composition is administered four to seven days prior to the administration of cyclophosphamide.

17. (Amended) The method of claim [10]13, wherein the tumor cells or tumor cell extracts originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.

18. (Amended) The method of claim [10]13, wherein the tumor cells or tumor cell extracts are autologous.

19. (Amended) The method of claim [10]13, wherein the tumor is melanoma.

20. (Amended) The method of claim [10]13, wherein the patient is a human.